1652

CERTIFICATE OF MAILING

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November 4, 2004
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Heidi A. Dare, Reg. No. 50,775
Name of Applicant, Assignee or
Registered Representative

Heidi A. Dare
Signature

November 4, 2004
Date of Signature

Our Case No.: 10114/6
Client Reference No.: 00-510

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Peng G. Wang et al.

Serial No.: 09/758,525

Filing Date: January 10, 2001

For: GLYCOCONJUGATE SYNTHESIS USING A PATHWAY-ENGINEERED ORGANISM

Examiner: Tekchand Saidha

Group Art Unit No.: 1652

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction/Election Requirement in the Office Action mailed October 4, 2004, Applicants provisionally elect the group drawn to (a) a sugar-nucleotide regenerating enzyme **GalK** and (b) a glycosyltransferase **LgtC** with traverse.

Applicants further elect claims directed to "host cells", claims 39-48 and 52-70. Applicants cannot identify to which group of the alleged 812 inventions the elected elements belong because the Examiner has failed to individually identify each of the 812 groups.

Applicants strenuously traverse the 812-way restriction requirement and respectfully request that the Examiner withdraw the restriction requirement from the application. Applicants intend to petition the Commissioner to review the requirement provided the Examiner makes the restriction requirement final.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." The term "independent" means that there is no disclosed relationship between the two or more subjects disclosed (MPEP § 802.01). The term "distinct" means that two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (MPEP § 802.01) (emphasis in original).

One purpose of the restriction requirement is to prevent patenting of distinct and independent inventions in the same application. The restriction is only properly required under the statute if one of two or more claimed inventions are able to support separate patents and they are either independent or distinct. Even when the inventions are shown to be patentably distinct, the Examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following according to MPEP § 808.02:

A. Separate classification

B. Separate status in the art; or

C. Different field of search.

Further, where the claims can be examined together without undue burden, the Examiner must examine the claims on the merits even though they are directed to independent and distinct inventions (MPEP § 803.01).

Applicants traverse this restriction for three reasons: (1) the Examiner has failed to establish that the 812 inventions are so patentably distinct to warrant separate examination, (2) the Examiner has failed to demonstrate that there is a burden, and (3) general fairness.

(1) Applicants respectfully assert that the Groups 1-812 designated by the Examiner fail to define inventions so distinct as to warrant separate examination and search. The Examiner has not shown how each of the sugar-nucleotide regenerating enzymes and glycosyltransferases are materially different so as to merit a restriction requirement. The Examiner has characterized each of the 406 host cell constructs as comprising a combination of two distinct genes and therefore, the Examiner states that each of the 406 groups is patentably distinct. Applicants respectfully submit that the Examiner has merely made a conclusion, and has not provided examples/explanation to suggest that these groups are patentably distinct, as alleged. Applicants respectfully point out that all of the enzymes encoded by the genes of the claimed invention are classified in class 435 and thus are not a separate classification. The Examiner has also not provided support that separate examination is required based on a separate status in the art or a different field of search is required.

The Examiner has characterized the relationship between the groups 1-406 and 407-812 as a process of making and a product being made. Citing MPEP § 806.05(f), the Examiner states that theses groups are distinct if the process can be used to make other and materially different products or that the product as claimed can be made by another and materially different process. The Examiner asserts that the claimed process can be used to make other and materially different products. However, the Examiner has failed to provide an example of a product made by the host cell not claimed in groups 1-406 that could be made by the method of groups 407-812. Applicants respectfully traverse the requirement for the restriction on the grounds that the Examiner has not provided adequate reasons and/or examples to support a conclusion of patentable distinctness between the 406 groups identified by the Examiner.

(2) Applicants respectfully assert that the Examiner has failed to establish that there is a burden if Groups 1-812 were searched together. The Examiner has not shown that each of the inventions identified as Groups 1-812 require a separate classification in the art, a separate status in the art if classified together or different fields of search. If anything, the Examiner has shown the exact opposite. The Examiner has already identified that the 14 glycosyltransferase enzymes of the present invention belong to a single subclass, class 435, subclass 252.3. Because a sugar-nucleotide regenerating enzyme and a glycosyltransferase are required in each of the independent claims, the Examiner would not be required to search for one of the subjects in places where no pertinent art to the other subject exists.

Applicants also assert that the Examiner has not shown that there is a serious burden on the Examiner (MPEP §803(B)). No evidence of separate recognition in the art has been provided. For the Markush-type claims, Applicants assert that the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden and the Examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions as required by MPEP §803.02. Searching a single subclass of glycosyltransferases should not present a serious search burden when searched together with the sugar-nucleotide regenerating enzymes.

(3) The present restriction leads Applicants to wonder how the PTO plans to proceed with examination in this case. To the extent that the PTO will require specific claims to the elected invention –how will the written description and enablement provisions of 35 U.S.C. § 112 be applied? Will the PTO require Applicants to file evidence demonstrating the enablement of each of the 812 different inventions? Will Applicants to be able to rely on experiments performed with non-elected embodiments? To the extent the PTO requires each invention to be individually demonstrated, this is significantly more evidence than would be required for the currently written genus claim. The PTO's restriction raises not only the specter of possible procedural harm, but is also raises a real and substantive harm. Applicants are a small entity and by restricting

the present application 812 ways, the PTO is requiring the Applicants to file 812 separate applications in order to cover the full scope of their invention. The filing fees for 811 additional applications at the current rate are $320,345. If all 812 applications issue, the issue fees would total $556,220. These are only the government fees. There are also legal fees associated with each application. Applicants cannot afford to prosecute 812 applications. This is simply unfair.

Reconsideration is respectfully solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

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Date: November 4, 2004 Name: Heidi A. Dare Signature: Heidi A. Dare

BRINKS HOFER GILSON & LIONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Peng G. Wang et al.

Appln. No.: 09/758,525 Examiner: Tekchand Saidha

Filed: January 10, 2001 Art Unit: 1652

For: GLYCOCONJUGATE SYNTHESIS USING A PATHWAY-ENGINEERED ORGANISM

Attorney Docket No: 10114/6

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Attached is/are:

☒ Transmittal (and copy)(2 pages); Response to Restriction Requirement (5 pages)

☒ Return Receipt Postcard

Fee calculation:

☒ No additional fee is required.

☐ Small Entity.

☐ An extension fee in an amount of $_____ for a _____-month extension of time under 37 C.F.R. § 1.136(a).

☐ A petition or processing fee in an amount of $_____ under 37 C.F.R. § 1.17(_____).

☐ An additional filing fee has been calculated as shown below:

					Small Entity			Not a Small Entity	
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra	Rate	Add'l Fee	or	Rate	Add'l Fee
Total	0	Minus	0	0	x $9=	0.00		x $18=	0.00
Indep.	0	Minus	0	0	x 44=	0.00		x $88=	0.00
First Presentation of Multiple Dep. Claim					+$150=	0.00		+ $300=	0.00
					Total	$0.00		Total	$0.00

Fee payment:

☐ A check in the amount of $_____ is enclosed.

☐ Please charge Deposit Account No. 23-1925 in the amount of $. A copy of this Transmittal is enclosed for this purpose.

☐ Payment by credit card in the amount of $_____ (Form PTO-2038 is attached).

☒ The Director is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and any patent application processing fees under 37 CFR § 1.17 associated with this paper (including any extension fee required to ensure that this paper is timely filed), or to credit any overpayment, to Deposit Account No. 23-1925.

Respectfully submitted,

November 4, 2004

Heidi A. Dare

Heidi A. Dare (Reg. No. 50,775)